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PATENT Case No. 2114-TTP

PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: D.J. MacNeil et al.

Serial No. 10/520,566

Filed: January 7, 2005

For: COMBINATION THERAPY FOR THE TREATMENT OF  
OBESITY

Art Unit: \_\_\_\_\_

Examiner: \_\_\_\_\_

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By Barbel R. Brown Date 3/22/05

## INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

Barbel R. Brown

By: BAERBEL R. BROWN

Attorney \_\_\_\_\_ For Applicant(s)

Reg. No. 47,449

MERCK & CO., INC.

Patent Dept., RY60-30

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(732)594-0672

Date: March 22, 2005



**COMPLETE IF KNOWN**

<b>Application Number</b>	10/520,566
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<b>Filing Date</b>	January 7, 2005
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<b>First Named Inventor</b>	D.J. MacNeil et al.
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### Group Art Unit

Examiner Name

Attorney Docket Number 21141YP

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of

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U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
			WO 97/20823		NOVARTIS AG	06/12/1997
			WO 98/18481		MERCK & CO., Inc.	05/07/1998
			WO 98/28427		AMGEN INC.	07/02/1998
			WO 99/33801		INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE	07/08/1999
			WO 00/66578		PFIZER PRODUCTS INC.	11/09/2000
			WO 00/76493		NAJARIAN	12/21/2000
			WO 01/14376		BANYU PHARMACEUTICAL CO., LTD.	03/01/2001
			WO 01/64675		NOVARTIS AG/NOVARTIS-ERFINDUNGEN VERWALTUNGSGESELLSCHAFT M.B.H.	09/07/2001
			WO 01/70337		MERCK & CO., Inc.	09/27/2001
			WO 01/70753		MERCK FROSST CANADA & CO.	09/27/2001

Examiner  
Signature

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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## STATEMENT BY APPLICANT

**COMPLETE IF KNOWN**

Attorney Docket Number	21141YP
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21141YP

[illegible][illegible]Date  
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# INFORMATION DISCLOSURE

## STATEMENT BY APPLICANT

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Group Art Unit	
Examiner Name	
Attorney Docket Number	21141YP

Sheet 4 of 5

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	AA	Parker et al., Eur. J. of Pharmacology, Vol. 440 (2002), pp. 173-187, "Neuropeptide Y receptors as targets for anti-obesity drug development ..."
	AB	Dax, Drugs of the Future (2002), Vol. 27(3), pp. 273-287, "Small-molecule neuropeptide Y Y5 antagonists"
	AC	Ford et al., JAMA (2002), Vol. 287, pp. 356-359, "Prevalence of the metabolic syndrome among US adults"
	AD	Gadde, et al., JAMA (2003), Vol. 289, pp. 1820-1825, "Zonisamide for weight loss in obese adults"
	AE	Rowland et al., Psychopharmacology (2001), Vol. 159, pp. 111-116, "Effects of the cannabinoid receptor antagonist SR 141716, alone and in combination with dexfenfluramine or naloxone, on food intake in rats"
	AF	Boozer et al., Metabolism, Vol. 50 (2001), pp. 889-893, "Synergy of sibutramine and low-dose leptin in treatment of diet-induced obesity in rats"
	AG	Matson et al., Am. J. Physiol. Regulatory Integrative Comp. Physiol., Vol. 278 (2000), pp. R882-R890, "Cholecystokinin and leptin act synergistically to reduce body weight"
	AH	Kopelman, Nature, Vol. 404 (2000), pp. 635-643, "Obesity as a medical problem"
	AI	Davidson et al., JAMA (1999), Vol. 281, pp. 235-242, "Weight control and risk factor reduction in obese subjects treated for 2 years with orlistat"
	AJ	de Vos et al., J. Biol. Chem., Vol. 270 (1995), pp. 15958-15961, "Induction of <i>ob</i> gene expression by corticosteroids is accompanied by body weight loss and reduced food intake"
	AK	Flier et al., Cell (1998), Vol. 92, pp. 437-440, "Obesity and the hypothalamus: Novel peptides for new pathways"
	AL	Abu-Elheiga et al., Science (2001), Vol. 291, pp. 2613-2616, "Continuous fatty acid oxidation and reduced fat storage in mice lacking acetyl-CoA carboxylase 2"
	AM	Smith et al., Nature Genetics, Vol. 25 (2000), pp. 87-90, "Obesity resistance and multiple mechanisms of triglyceride synthesis in mice lacking Dgat"
	AN	Cummings et al., Nature, Vol. 382 (1996), pp. 622-626, "Genetically lean mice result from targeted disruption of the RIIβ subunit of protein kinase A"
	AO	Wadden et al., Obesity Research, Vol. 8 (2000), pp. 431-437, "Effects of sibutramine plus orlistat in obese women following 1 year of treatment by sibutramine alone ..."

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Attorney Docket Number	21141 YP

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	AP	Menzio et al., British J. of Nutrition, Vol. 84 (2000), pp. 515-520, "Resting metabolic rate, fat-free mass and catecholamine excretion during weight loss in female obese patients"
	AQ	Sorribas et al., J. Pharm. Pharmacol., Vol. 44 (1992), pp. 1030-1032, "Effects of nicarbazin on intestinal digestion and absorption of nutrients in the rabbit"
	AR	Badr et al., Toxicology, Vol. 34 (1985), pp. 333-340, "Potentiation of methotrexate-induced gastrointestinal toxicity by non-steroidal anti-inflammatory drugs (NSAIDs) and vincristine"
	AS	Stanley et al., Peptides, Vol. 13 (1992), pp. 581-587, "Evidence for neuropeptide Y mediation of eating produced by food deprivation and for a variant of the Y1 receptor mediating this peptide's effect"
	AT	Guy-Grand et al., The Lancet, Vol. 2 (1989), pp. 1142-1145, "International trial of long-term dexfenfluramine in obesity"
	AU	Sahu et al., Trends Endocrinol. Metab., Vol. 4 (1993), pp. 217-224, "Neuropeptidergic regulation of feeding behavior"
	AV	Wolf, Nutrition Reviews, Vol. 59, No. 2 (2001), pp. 56-57, "The uncoupling proteins UCP2 and UCP3 in skeletal muscle"
	AW	Bray et al., Obesity Res., Vol. 7, No. 2 (1999), pp. 189-198, "Sibutramine produces dose-related weight loss"
	AX	Douglas et al., Int'l J. of Obesity, Vol. 7 (1983), pp. 591-595, "Plasma phentermine levels, weight loss and side-effects"

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